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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,760

11/01/2005

Udo J. Vetter

2693-000011/NP

7842

27572 7590 10/16/2008  
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EXAMINER

BHATIA, AARTI

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/535,760	<b>Applicant(s)</b> VETTER ET AL.	
	<b>Examiner</b> Aarti Bhatia	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/27/2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the initial Office Action based on the 10/535,760 application filed on 5/20/2005.

Claims 1-12, as amended on 6/27/2008, are currently pending and have been considered below.

### ***Response to Amendment***

1. The objections to the specification have been withdrawn in view of the amendments provided by the Applicant.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,688,252 to Matsuda et al.

Matsuda discloses the following:

1. A prefilled medical syringe (figure 6, (K1)) comprising: a syringe barrel (1) enclosing an inner space (5,6); a syringe plunger (2) disposed in the space and coupled to a first end of a plunger rod (3) having an outer thread (31) that is formed between the first end and a second end (see 31 in figure 6); an end plug closing off a cannula end of the syringe barrel, the end plug (7) having a through-channel (10) closed off by a membrane; a finger support (11) disposed on an end of the syringe barrel opposite the

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end plug and having a through-opening (1b) for the plunger rod; and a thread system (21) that cooperates with the plunger rod and with the finger support the thread system having a thread sleeve with an internal thread that cooperates with an outer thread (31) on the plunger rod (3), the thread sleeve being detachably connected with the finger support and coupled with the plunger rod for common displacement into the inner space (figure 10).

2. The syringe of claim 1, wherein the thread sleeve is pressed (slidably inserted) into the base of the finger support (column 8, lines 62-64).

4. The syringe of claim 1 (figure 6), wherein there is provided a pin (10) that can be brought into contact with the membrane (7).

5. The syringe of claim 1, wherein the thread system (21) is configured as a separate part (see figure 6).

12. The syringe of claim 1, wherein the outer thread is formed a distance from the first end (a portion of the thread is spaced a distance from the first end, see figure 6).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda et al.

Matsuda discloses the syringe of claim 1, but fails to teach wherein the thread sleeve is coupled with the finger support in a positively locking manner.

However, since the thread sleeve/gasket (21/2) of Matsuda is held at the base of the finger support until it is coupled with the male screw/plunger rod (31/3), it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the thread sleeve coupled with the finger support in a "positively locking

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manner”, so that movement of the thread sleeve does not occur until it is coupled with the plunger rod.

8. Claims 6-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuda et al.

Matsuda discloses the prefilled medical syringe as substantially claimed, but fails to teach a membrane that is ruptured by a pin in response to the pressure created by the mating of the treaded sections.

When the threaded sections of Matsuda are engaged and the plunger pushed, pressure will increase in the inner space thereby causing the fluid to escape via the needle. It would be obvious to one having ordinary skill in the art at the time the invention was made to modify the membrane of Matsuda with a pin, to prevent loss of fluid from the syringe until the user engaged the threaded sections together.

### ***Response to Arguments***

9. Applicant's arguments filed 6/27/2008 have been fully considered but they are not persuasive.

10. The Applicant argues that Matsuda fails to teach a threaded section between the two ends of the plunger rod. The Examiner disagrees. See rejection above.

11. The Examiner appreciates the differences between the threaded sections of Matsuda and the present application, however, Matsuda anticipates claim 1 as currently presented.

***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763